

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Venu B. Reddy et al.  
Serial No. 24: DEC 8, 1983  
Filed: November 2, 1983  
For: HETERO POLYMERIC PROTEINS

Group Art 174

Commissioner of Patents and Trademarks  
Washington, DC 20231

Declaration of Arthur Skoultchi  
under 37 C.F.R. §1.132

I declare:

- 1) I hold the degree of Ph.D. in <sup>Bio</sup>Physics from Yale University; my current position is Professor of Cell Biology, Albert Einstein Medical School; and I have published articles in the field of molecular genetics.
- 2) I have read the above-captioned patent applicaiton, and the Office Action mailed July 26, 1985.
- 3) I could not have predicted the production of a biologically active heterodimeric hormone in undifferentiated cells transformed with DNA encoding the alpha and beta subunits prior to its accomplishment by the above-named inventors, for the following reasons:
  - a) Heterodimeric fertility hormones are produced in the body by highly specialized, differentiated cells which have evolved over a long period of time to carry out the specialized function of producing each particular hormone.
  - b) The mechanism by which post-translational heterodimer assembly occurs intracellularly in these differentiated cells is not known, but it is known

that proper assembly is necessary for biological activity.

c) Undifferentiated cells do not, as far as is known, normally produce hormones, and thus I could not have predicted that such cells would be capable of properly assembling a heterodimeric, biologically active hormone.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Arthur Skoultchi  
Arthur Skoultchi

Date: November 14, 1985